Office - Supreme Court, U.S.
FILED
AUG 31 1984
ALEXANDER L. STEVAS,
CLERK

No. 84-130

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,

v.

ROCHE PRODUCTS INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF RESPONDENT IN OPPOSITION

JOHN C. VASSIL
345 Park Avenue
New York, New York 10154
(212) 758-4800
Counsel of Record for Respondent

Of Counsel:

STEPHEN R. SMITH
J. ROBERT DAILEY
JANET DORE
MORGAN, FINNEGAN, PINE, FOLEY & LEE

JACK LIPSON
MICHAEL T. SHOR
ARNOLD & PORTER
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036

RALPH N. DEL DEO
Crummy, Del Deo, Dolan & Purcell
A Professional Corporation
Gateway 1
Neward, New Jersey 07102
07102

August 31, 1984

BEST AVAILABLE COPY

COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. Should this Court review the holding of the Court of Appeals for the Federal Circuit that the unauthorized use of a patented compound during the term of the patent solely for the user's business purposes constitutes infringement of that patent under 35 U.S.C. § 271(a)?

2. Should this Court grant certiorari to determine whether the Court of Appeals for the Federal Circuit erred in refusing to create a new exception to the patentee's right to exclude others from use of his patented invention during the seventeen-year term of his valid patent, as codified in the plain language of the patent statute (35 U.S.C. § 271(a)) and recognized for nearly 200 years of patent law, when the use by the infringer admittedly was to prepare to market commercially the patented invention and the infringer expressly conceded that the use was not within the scope of the experimental use exception?

PARTIES TO THE PROCEEDINGS BELOW

The parties named in the caption are the only parties to this action. Respondent's statement pursuant to Rule 28.1 is set forth in the margin.*

* Roche Products Inc. is a Panamanian corporation licensed to do and doing business in Puerto Rico. It is wholly owned by Caribbean Trade and Holding Company Limited SA (a Panamanian corporation) which in turn is a wholly owned subsidiary of Sapac Corporation, Ltd. of New Brunswick, Canada ("Sapac"). The voting shares of Sapac are held in trust for the benefit of F. Hoffmann-LaRoche & Co. Limited Company, Basle, Switzerland, a Swiss corporation ("Roche Basle"). Sapac's non-voting shares are linked to the shares of Roche Basle. The linked shares are publicly owned, quoted and traded in Switzerland. Roche Products Inc. has no affiliation with any companies apart from members of the Roche Basle and Sapac group of companies.

TABLE OF CONTENTS

	Page
COUNTERSTATEMENT OF QUESTIONS PRESENTED	i
PARTIES TO THE PROCEEDINGS BELOW	ii
TABLE OF AUTHORITIES	iv
OPINIONS BELOW	1
COUNTERSTATEMENT OF THE CASE	2
REASONS FOR DENYING THE WRIT	4
I NO JUSTIFICATION WARRANTING REVIEW OF THE COURT OF APPEALS WITH NATIONWIDE JURISDICTION OVER PATENT APPEALS IS PRESENT IN THIS CASE	5
II IN DECIDING THAT BOLAR'S ACTIVITIES FELL OUTSIDE THE SCOPE OF PERMISSIBLE "EXPERIMENTAL USE," THE CAFC APPLIED WELL-ESTABLISHED PRINCIPLES	6
A. It Is Hornbook Patent Law that the Use of a Patented Compound for Purposes of Commercially Exploiting that Compound Cannot Be Considered a Non-Infringing "Experimental Use"	6
B. This Court Should Decline To Expand the "Experimental Use" Exception	9
III THE PATENT CASES RELIED UPON BY BOLAR DO NOT SANCTION ITS INFRINGING USE OF ROCHE PRODUCTS' PATENT DURING THE PATENT TERM	11
IV THERE IS NO CONFLICT BETWEEN THE CAFC'S DECISION AND DECISIONS OF THIS COURT PROHIBITING THE EXTENSION OF PATENT "MONOPOLIES"	13
CONCLUSION	15

TABLE OF AUTHORITIES

	Page
CASES	
Adams v. *Burke*, 84 U.S. 453 (1873)	12
Akro Agate Co. v. *Master Marble Co.*, 18 F. Supp. 305 (N.D. W. Va. 1937)	13
Albright v. *Celluloid Harness-Trimming Co.*, 1 F. Cas. 320 (C.C.D.N.J. 1887) (No. 147)	12
Becton Dickinson & Co. v. *R.P. Scherer Corp.*, 211 F.2d 835 (6th Cir. 1954)	11
Beedle v. *Bennett*, 122 U.S. 71 (1887)	11
Brulotte v. *Thys Co.*, 379 U.S. 29 (1964)	13
Carter Crume Co., Ltd. v. *American Sales Book Co.*, 124 F. 903 (C.C.W.D.N.Y. 1903)	12
Celotex Corp. v. *V.E. Power Door Corp.*, 204 U.S.P.Q. 636 (E.D.N.Y. 1979)	13
Del Mar Engineering Laboratories v. *Physio-Tronics, Inc.*, 202 U.S.P.Q. 242 (C.D. Cal. 1978), *aff'd*, 642 F.2d 1167 (9th Cir. 1981)	11-12
Flat Slabs Patents Co. v. *Wright, Barrett & Stilwell Co.*, 283 F. 345 (D. Minn. 1920)	12
Fulton Co. v. *Bishop & Babcock Co.*, 17 F.2d 1006 (6th Cir. 1927)	14
Kaz Mfg. Co., Inc. v. *Chesebrough-Pond's, Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd*, 317 F.2d 679 (2d Cir. 1963)	12
Keeler v. *Standard Folding Bed Co.*, 157 U.S. 659 (1895)	12
Kellogg Co. v. *National Biscuit Co.*, 305 U.S. 111 (1938)	14
Levin v. *Ripple Twist Mills, Inc.*, 416 F. Supp. 876 (E.D. Pa. 1976), *appeal dismissed*, 549 F.2d 795 (3d Cir. 1977)	13
Maxon Premix Burner Co. v. *Eclipse Fuel Engineering Co.*, 471 F.2d 308 (7th Cir. 1972), *cert. denied*, 410 U.S. 929 (1973)	13
Mercoid Corp. v. *Mid-Continent Investment Co.*, 320 U.S. 661 (1944)	11

	Page
Motion Picture Patents Co. v. *Centaur Film Co.*, 217 F. 247 (D.N.J. 1914)	14
Neff Instrument Corp. v. *Cohu Electronics, Inc.*, 269 F.2d 668 (9th Cir. 1959)	11
Pfizer, Inc. v. *International Rectifier Corp.*, 217 U.S.P.Q. 157 (C.D. Cal. 1982)	8
Pitcairn v. *United States*, 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978)	8
Poppenhusen v. *Falke*, 19 F. Cas. 1048 (C.C.S.D.N.Y. 1861) (No. 11, 279)	7
Radio Corp. of America v. *Andrea*, 15 F. Supp. 685 (E.D.N.Y. 1936), *modified on other grounds*, 90 F.2d 612 (2d Cir. 1937)	8,14
Roche Products, Inc. v. *Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984)	*passim*
Scott Paper Co. v. *Marcalus Mfg. Co.*, 326 U.S. 249 (1945)	14
Singer Mfg. Co. v. *June Mfg. Co.*, 163 U.S. 169 (1896)	14
Technicon Instruments Corp. v. *Coleman Instruments, Inc.*, 255 F. Supp 630 (N.D. Ill. 1966), *aff'd*, 385 F.2d 391 (7th Cir. 1967)	12
Underwood Typewriter Co. v. *Elliott-Fisher Co.*, 156 F. 588 (C.C.S.D.N.Y. 1907)	14
United States v. *General Electric Co.*, 272 U.S. 476 (1926)	12
United States v. *Generix Drug Corp.*, 460 U.S. 453, 103 S. Ct. 1298 (1983)	4
Upjohn Mfg. Co. v. *Schweiker*, 681 F.2d 480 (6th Cir. 1982)	14
Whittemore v. *Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No.17,600)	7
STATUTES	
28 U.S.C. § 1295	5
28 U.S.C. § 1338	5
35 U.S.C. § 154	2,6
35 U.S.C. § 261	12

	Page
35 U.S.C. § 271(a)	2,6,12
35 U.S.C. § 281	5
Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982)	5
CONGRESSIONAL MATERIAL	
H.R. 3605, Patent Restoration and Related Bills: Hearing Before the Subcomm. on Civil Liberties and the Admin. of Justice of the House Comm. on the Judiciary, 89th Cong., 2d Sess. 22 (June 27, 1984)	8
H.R. Rep. No. 312, 97th Cong., 1st Sess. (1981)	5
S. Rep. No. 275, 97th Cong., 1st Sess. (1981)	5
S. 2926, 98th Cong., 2d Sess. § 202, 130 Cong. Rec. § 10512 (daily ed. Aug. 10, 1984)	10
127 Cong. Rec. H8390 (daily ed. Nov. 17, 1982)	6
MISCELLANEOUS	
Bee, *Experimental Use as an Act of Patent Infringement,* 39 J. Pat. Off. Soc'y 357 (1957)	7
C. Haworth & C. Meader, *A Proposed New Federal Intermediate Appellate Court,* 12 Univ. Mich. J. Law Reform 201 (1979)	5
3 W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890)	8-9
48 C.J., *Patents* § 496 (1929)	9
69 C.J.S., *Patents* § 288 (1951)	9

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

No. 84-130

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,

v.

ROCHE PRODUCTS INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

---

BRIEF OF RESPONDENT IN OPPOSITION

Respondent, Roche Products Inc. ("Roche Products"), respectfully requests that the Court deny Bolar Pharmaceutical Co., Inc.'s ("Bolar") Petition for a Writ of Certiorari. Neither the questions presented nor the reasons given by petitioner for grant of the writ provide appropriate bases for the exercise of this Court's discretionary jurisdiction.

OPINIONS BELOW

The decision of the District Court for the District of New Jersey granting Roche Products a temporary restraining order is unpublished but is reproduced at 21a-27a.[1] The opinion of the District Court for the Eastern District of New York holding non-infringement and denying Roche Products an injunction is

[1] Appendix references will be to the numbered pages of the Appendices to Bolar's Petition.

reported at 572 F. Supp. 255 (1983) (31-37a). The opinion of the Court of Appeals for the Federal Circuit ("CAFC") reversing the District Court is reported at 733 F.2d 858 (1984) (1a-18a), and its judgment is reproduced at 39a. The mandate of the CAFC issued on May 15, 1984.

COUNTERSTATEMENT OF THE CASE

This action involves the use by Bolar of Roche Products' patented invention, flurazepam hydrochloride, in the closing months of the patent's term for Bolar's own business purposes.[2] Roche Products' patent is admitted to be for a pioneer invention and to be valid and enforceable (32a). Bolar has also admitted it possessed the patented compound and intended to use it prior to the expiration of the patent in conducting the tests required to obtain Food and Drug Administration ("FDA") approval to market commercially its generic version of Roche Products' DALMANE brand prescription product (33a). The actual extent of Bolar's use will be determined by the district court below on remand. The parties have acknowledged that Roche Products had not authorized Bolar to make, use or sell flurazepam (33a).

Roche Products filed suit for declaratory judgment and injunctive relief to enforce its right to exclude Bolar from "making, using or selling" the patented invention during the life of the patent (35 U.S.C. §§ 154, 271(a)). The CAFC found that Bolar's intended use of flurazepam was solely for business reasons and held that such use constituted infringement of Roche Products' patent (9a).

Bolar terms Roche Products' successful enforcement of its vested legal rights "patent extension." Such terminology is misleading because it implies, incorrectly, that the decision

---

[2] Roche Products owns patent 3,299,053 by mesne assignments from the original owner, Hoffmann-LaRoche Inc. of Nutley, N.J., which in turn obtained rights to the patent and the invention from its employee inventors. The patented compound, flurazepam hydrochloride, will be referred to hereinafter as "flurazepam" for convenience. Capsules for oral administration containing 15 mg. or 30 mg. of flurazepam as the active ingredient are the standard dosage forms of the DALMANE brand prescription product marketed by Roche Products.

below alters the term of Roche Products' patent. That term was fixed, by statute, at seventeen years as of the date the patent was granted on January 17, 1967, and has not been extended even one day by the decision below. Immediately upon the expiration of the patent, on January 17, 1984, Bolar and all others were free to make, use and sell flurazepam.

Bolar's inability to market flurazepam as a dosage form prescription product (*i.e.*, as its generic version of DALMANE) immediately upon the expiration of Roche Products' patent is simply a collateral consequence of the FDA regulatory process. This regulatory process had delayed Roche Products' predecessor's ability to market dosage form flurazepam products just as severely as it now delays Bolar. Roche Products' predecessor also had to obtain FDA approval prior to marketing flurazepam products. Documents publicly available from the FDA and the Patent Office reveal that Roche Products' predecessor submitted its Investigational New Drug Application to the FDA in August 1963, applied for its patent in February 1964, obtained the patent in January 1967, submitted its New Drug Application to the FDA in November 1967, and obtained approval from the FDA in April 1970. Thus, by the time Roche Products' predecessor received FDA approval to market DALMANE, it had already lost more than three years of the seventeen year life of the patent.

Significantly, Bolar's intended and actual use of flurazepam during the patent term had but one purpose—the commercial exploitation of that compound. Its FDA-related testing activities would not and could not be characterized as research and development, because Bolar never intended or expected to discover a new substance or anything innovative. In order to obtain regulatory approval, Bolar would first have to determine what fillers, binders and excipients it should use with flurazepam in formulating its generic dosage form. Second, it would have to perform stability, dissolution and bioequivalency tests to demonstrate to the FDA that its product is comparable to Roche Products' DALMANE. Neither of these steps is innovative.

The process of producing a generic equivalent to a patented drug is not one of innovation and creativity; it is one of copying. As this Court has noted:

> "Generic drugs, also called 'copycat' or 'me-too' drugs, are usually marketed at relatively low prices because their manufacturers do not incur the research, development, and promotional costs normally associated with the creation and marketing of an original product." *United States* v. *Generix Drug Corp.*, 460 U.S. 453, 103 S. Ct. 1298, 1299 n.1 (1983).

Such commercially based use does not fall within the recognized limits of permissible experimental use as Bolar now suggests. Bolar conceded as much before both the district court and the CAFC, and the CAFC properly declined to create a new exception to permit such an encroachment on Roche Products' statutory property rights.

Bolar asserts that it was common practice and custom for drug companies to use a patented product for FDA testing and approval "well in advance" of patent expiration without objection from the patentee. (Pet. at 4.) While an affidavit alleging such a practice was filed by Bolar in the district court, the claim was disputed by Roche Products. Bolar offered no independent evidence to support its claim, and the district court did not find that any such practice existed. Bolar abandoned the contention on appeal. The practice and custom to which Bolar refers does not exist.

REASONS FOR DENYING THE WRIT

This case does not meet the accepted standards for discretionary review. There is no conflict between the CAFC's decision and a prior decision of another court of appeals, and none is alleged. No conflict exists between the CAFC's decision and a decision of the highest court of any state, and no conflict exists between the CAFC's decision and any decision of this Court, notwithstanding Bolar's assertion to the contrary. Finally, the CAFC's decision does not decide any new and

important issues of federal law which should be settled by this Court. Rather, the CAFC decision applies well-settled principles of patent law.[3]

I

NO JUSTIFICATION WARRANTING REVIEW OF THE COURT OF APPEALS WITH NATIONWIDE JURISDICTION OVER PATENT APPEALS IS PRESENT IN THIS CASE

In 1982, Congress conferred upon the newly established CAFC exclusive appellate jurisdiction over patent-related cases.[4] 28 U.S.C. §§ 1295(a)(1) and (4). The intent of Congress was to "reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in the administration of patent law." H.R. Rep. No. 312, 97th Cong., lst Sess. 23 (1981) (hereinafter "House Report").[5]

Congress intended that the CAFC's patent decisions would have special authoritativeness, expressly recognizing that "[d]ecisions of this court will have precedential effect throughout the country; . . ." S. Rep. No. 275, 97th Cong., 1st Sess. 7 (1981). Congress contemplated that the need for Supreme Court review of patent law decisions would thereby be lessened. As the bill's sponsor in the House (and chairman of the subcommittee responsible for reporting the bill) stated before

---

[3] The additional attempt by Bolar to inject a factual issue of alleged practice and custom, after abandoning that same issue below, is plainly inappropriate in a petition for certiorari (32a).

[4] The CAFC was established, and its jurisdiction defined, by the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982) (hereinafter "Courts Act").

[5] The Court of Customs and Patent Appeals, which was replaced by the CAFC, did not have exclusive jurisdiction over patent-related appeals. Several appellate fora were available, depending upon the nature of the action. For example, jurisdiction of suits for infringement of patents or for declaratory judgments of noninfringement was and remains vested in the federal district courts. 28 U.S.C. § 1338; 35 U.S.C. § 281. The Courts Act, however, transferred appellate jurisdiction from the twelve circuit courts of appeals to the CAFC. *See* 28 U.S.C. § 1295(a)(2). *See generally* C. Haworth & C. Meader, *A Proposed New Federal Intermediate Appellate Court*, 12 Univ. Mich. J. Law Reform 201, 215-17 (1979); House Report at 22.

the full House in introducing the bill, the CAFC "will relieve docket pressure both on the regional appellate courts *and on the Supreme Court.*" 127 Cong. Rec. H8390 (daily ed. Nov. 17, 1981) (statement of Rep. Kastenmeier) (emphasis added).

In light of the congressional purpose in establishing the CAFC, there is no reason for this Court to review purely patent law issues where no conflict exists with other federal courts and where the CAFC merely has applied well-established law defining the scope of permissible "experimental use."

II

IN DECIDING THAT BOLAR'S ACTIVITIES FELL OUTSIDE THE SCOPE OF PERMISSIBLE "EXPERIMENTAL USE," THE CAFC APPLIED WELL-ESTABLISHED PRINCIPLES

A. It Is Hornbook Patent Law that the Use of a Patented Compound for Purposes of Commercially Exploiting that Compound Cannot Be Considered a Non-Infringing "Experimental Use"

Bolar concedes that Roche Products' patent was valid (32a). It is also uncontested on this record that Bolar, without waiting for that patent to expire, intended to use the patented compound in order to obtain approval from the FDA for post-expiration marketing. As the CAFC stated:

> "In mid-1983, Bolar obtained from a foreign manufacturer 5 kilograms of flurazepam hcl to form into 'dosage form capsules, to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies' necessary for a New Drug Application to the United States Food and Drug Administration (FDA)." (2a)

Bolar's activities plainly fell within the proscriptions of 35 U.S.C. §§ 154 and 271(a), which grant to a patent holder the right to exclude others from making, *using* or selling the patented invention. Despite concessions below, Bolar now asserts that its activities fell within the "experimental use" exception to infringement. Plainly, they do not. That narrow

exception, as defined correctly by the CAFC, applies only to experiments performed on the patented compound for the limited purposes of amusement, to satisfy idle curiosity, or for strictly philosophical inquiry—what we would today call scientific inquiry (6a). *See Whittemore* v. *Cutter,* 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600); *Poppenhusen* v. *Falke,* 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279). *See also* Bee, *Experimental Use as an Act of Patent Infringement,* 39 J. Pat. Off. Soc'y 357 (1957).

The CAFC found that Bolar's unlicensed experiments were conducted with a view to the use of the patented invention in Bolar's business and held this to be a violation of the right of Roche Products to exclude others from using the invention (9a). The CAFC recognized that "no case had permitted a pattern of systematic exploitation of a patented invention for the purpose of furthering the legitimate business interests of the infringer" (9a). Bolar's tests and experiments constitute such systematic exploitation and, as found by the CAFC, were "solely for business reasons" (9a).

The experimental use exception, which Bolar now embraces in this Court (Pet. at 16-20), was expressly disavowed by Bolar before both the district court and the CAFC. In the district court:

> "Bolar concede[d] that its tests do not fall under the infringement exception known as experimentation for philosophical, amusement or curiosity purposes." (33a)

Again on appeal:

> "Bolar concede[d], as it must, that its intended use of flurazepam hcl does not fall within the 'traditional limits' of the experimental use exception as established in these cases or those of other circuits. Its concession here is fatal." (8a)

Indeed, the instant case was not a case of first impression. The decision by the CAFC is consistent with almost 200 years of interpretation of the patent laws upholding the principle that "experimental use" does not, under the guise of experimentation, sanction infringing use that is undertaken

"solely for business reasons" (9a) and which is "commercial preparation" (35a) and not "experimental" within the meaning of the patent law.[6]

In *Pfizer, Inc.* v. *International Rectifier Corp.*, 217 U.S.P.Q. 157 (C.D. Cal. 1982), the District Court for the Central District of California held that "[*e*]*very* use" of a patented compound, including use to obtain FDA approval so that the defendant would be "fully equipped and ready to go" into the "domestic and foreign" markets as soon as the patent expired, constituted infringement. *Id.* at 162 (emphasis added). Thus, the two reported cases addressing the specific question petitioner presents to this Court are in complete accord.

Both the decision in *Pfizer* and the decision below recognize as fundamental the principle that the experimental use exception does not apply to one who uses a patented invention for a commercial purpose. Moreover, the Honorable Gerald J. Mossinghoff, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, recently testified that the CAFC's decision below "really amounts to hornbook patent law in my opinion." *H.R. 3605, Patent Restoration and Related Bills: Hearing Before the Subcomm. on Civil Liberties and the Admin. of Justice of the House Comm. on the Judiciary,* 98th Cong., 2d Sess. 22 (June 27, 1984) (statement of Gerald J. Mossinghoff) (awaiting publication).

Additionally, a classic authority, which was relied upon by the CAFC and which was cited—but only partially quoted—by Bolar in its petition, states as follows:

> "[W]here it [the patented article] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promo-

---

[6] *See Pitcairn* v. *United States*, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978) ("[t]ests, demonstrations, and experiments . . . [which] are in keeping with the legitimate business of the . . . [infringer]" are infringements for which "[e]xperimental use is not a defense"); *Radio Corp. of America* v. *Andrea*, 15 F. Supp. 685 (E.D.N.Y. 1936), *modified on other grounds*, 90 F.2d 612 (2d Cir. 1937) (use of patented invention by testing in preparation for non-infringing extraterritorial sale held infringement).

> tion of the employer's knowledge or the realization afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent." 3 W. Robinson, *The Law of Patents for Useful Inventions* § 898 at 56 (1890).[7]

Consequently, when the CAFC refused to excuse Bolar's infringing activities, it simply enforced the law as it had been known and applied for years and refused to "create a new exception to the use prohibition" (10a).

B. This Court Should Decline To Expand the "Experimental Use" Exception

The CAFC correctly recognized that true "scientific inquiry" is exempted from patent infringement by the traditional "experimental use" exception. Bolar's argument, that the CAFC decision will prevent meaningful research and development and will stifle scientific creativity, is disingenuous. Neither the court's holding nor its language gives rise to any suggestion that the decision would restrict or delay "scientific inquiry." In its decision, the CAFC stated:

> "unlicensed experiments conducted with a view to adaption of the patented invention to the experimentor's business is a violation of the rights of the patentee. . . . We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes." (9a-10a)

---

[7] *Accord* 48 C.J., *Patents* § 496 (1929); 69 C.J.S., *Patents* § 288 (1951), stating: "Experimental use of a patented invention for the sole purpose of gratifying curiosity or a philosophical taste, or for mere amusement, is not an infringement. . . . This rule, however, cannot be invoked for the protection of one who uses a patented invention commercially, as in the course of business or for profit."

Bolar's suggestion that the experimental use exception should embrace its activities simply because they can be characterized as "tests" blurs the line between true experimental inquiries, *i.e.,* inquiries solely for scientific or philosophical purposes, and commercially oriented testing which is infringing. The CAFC recognized that labeling commercial activities as "scientific inquiry" does not make them such. Bolar admitted, and the district court and the CAFC both found, that Bolar's "tests and experiments" constituted commercial preparation for marketing dosage form products containing the patented compound (35a, 9a). These were not innovative scientific inquiries designed to expand the scope of human knowledge; rather, Bolar was simply using Roche Products' invention and seeking a "copycat" pharmaceutical product.

Bolar also admitted, in its brief before the CAFC, that these experiments and tests would overlap the *normal* manufacturing and formulation requirements it would undertake in preparation for marketing dosage form prescription products containing flurazepam, irrespective of any FDA requirements. Brief for Appellee at 7, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.,* 733 F.2d 858 (Fed. Cir. 1984). Bolar's admissions illustrate vividly the Pandora's box of patent infringement litigation which would surely be opened if the definition of experimental use is expanded or a new exception is created.[8] As Judge Sarokin wisely noted in granting the restraining order against Bolar: "[t]o hold otherwise would require a case by case determination of when such preparation could begin and what could be done in expectation of the expiration of the patent" (23a).[9]

---

[8] The use of a patented invention in carrying out various business activities preparatory to commercial exploitation of the invention, which use heretofore has clearly been within the patentee's right to exclude, could arguably be sanctioned in case after case under the guise of obtaining some form of approval, regulatory or otherwise.

[9] Any argument to broaden the experimental use exception to take from patent owners valuable property rights, such as Bolar now urges, is more properly addressed to Congress for such action as may be appropriate within the constraints imposed by the Fifth Amendment's taking clause. Congress is now considering legislation that would affect, to some extent, the scope of experimental use in the future. *See* S. 2926, 98th Cong., 2d Sess. § 202, 130 Cong. Rec. S10512 (daily ed. Aug. 10, 1984).

III

THE PATENT CASES RELIED UPON BY BOLAR DO NOT SANCTION ITS INFRINGING USE OF ROCHE PRODUCTS' PATENT DURING THE PATENT TERM

Bolar's strained interpretation of a series of decisions by this and other courts, if accepted, would excuse from infringement unauthorized uses of the patented invention even if such uses were systematic commercial activities. The CAFC was correct in refusing Bolar's invitation to expand the experimental use exception, or to create a new exception, so as to embrace such systematic commercial activities on the part of Bolar. Moreover, the CAFC reached its conclusion after considering the same cases and arguments relied on in Bolar's petition and discussed *infra*.

Bolar implies that the *only* right of the patent holder is "a right to be free from competition in the practice of the invention" during the term of the patent, (Pet. at 12,14) citing *Mercoid Corp.* v. *Mid-Continent Investment Co.*, 320 U.S. 661, 665 (1944), and that Bolar's use does not interfere with that right (Pet. at 13). These arguments are predicated on a misreading of *Mercoid* and a fundamental misapprehension of the patent law.

First, *Mercoid* does not hold that the *only* right a patentee has is the right to be free from competition in the marketplace. In *Mercoid, supra,* at 665, Justice Douglas actually wrote that "*a right*" conferred by a patent is the right to be free from competition, *i.e.,* the right to exclude others from selling. The opinion nowhere stated or indicated that this was the *only* right. The CAFC also held expressly there need not be sales or competition or profit in order to have infringement (4a).[10]

---

[10] Such has been the law as enunciated in numerous decisions decided before and after *Mercoid*. *See, e.g., Beedle* v. *Bennett*, 122 U.S. 71 (1887) (competition or profit not required); *Neff Instrument Corp.* v. *Cohu Electronics, Inc.*, 269 F.2d 668, 673 (9th Cir. 1959) (sales not required); *Becton Dickinson & Co.* v. *R.P. Scherer Corp.*, 211 F.2d 835, 842 (6th Cir. 1954) (sales not required); *Del Mar Engineering Laboratories* v. *Physio-Tronics, Inc.*, 202 U.S.P.Q. 242, 260 (C.D. Cal. 1978), *aff'd*, 642 F.2d 1167 (9th Cir.

(footnote continues)

Second, the statute itself establishes that the right to exclude others from selling the patented invention is only one of several rights and not the *only* right granted the patentee. The statute gives the patentee the right to exclude others from making *or* using *or* selling the invention. 35 U.S.C. § 271(a). These rights are property rights, 35 U.S.C. § 261, and are severable. "The right to manufacture, the right to sell, and the right to use are each substantive rights, and may be granted or conferred separately by the patentee." *Adams* v. *Burke*, 84 U.S. 453, 456 (1873).[11]

Furthermore, the existing case law does not support Bolar's claim that it has a right to use a patented product for commercial exploitation. *Kaz Mfg. Co., Inc.* v. *Chesebrough-Pond's, Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd*, 317 F.2d 679 (2d Cir. 1963), cited by Bolar, is inapposite. There the defendant had purchased the product from the patentee and had thereby acquired an implied license to use it. *See Keeler* v. *Standard Folding Bed Co.*, 157 U.S. 659 (1895). Here, Bolar's purchase of flurazepam was from an unauthorized source and Bolar cannot claim any implied license to use. Moreover, the challenged use in *Kaz* consisted of a single isolated use for the purpose of a comparative television advertisement. It was not the systematic exploitation contemplated by Bolar in this case.

(footnote continued)

1981) (sales not required); *Technicon Instruments Corp.* v. *Coleman Instruments, Inc.*, 255 F. Supp. 630, 641-42 (N.D. Ill. 1966), *aff'd*, 385 F.2d 391 (7th Cir. 1967) (sales not required); *Carter Crume Co., Ltd.*, v. *American Sales Book Co.*, 124 F. 903, 904 (C.C.W.D.N.Y. 1903) (sales not required); *Flat Slabs Patents Co.* v. *Wright, Barrett & Stilwell Co.*, 283 F. 345, 349 (D. Minn. 1920) (competition or profit not required); *Albright* v. *Celluloid Harness-Trimming Co.*, 1 F. Cas. 320 (C.C.D.N.J. 1887) (No. 147) (damage or profit not required).

[11] Still another valuable right conferred by a patent is the right to grant licenses. Thus, "the patentee may grant a license . . . for any royalty, or upon any condition the performance of which is reasonably within the reward which the patentee by the grant of his patent is entitled to secure." *United States* v. *General Electric Co.*, 272 U.S. 476, 489 (1926).

Akro Agate Co. v. *Master Marble Co.*, 18 F. Supp. 305 (N.D. W. Va. 1937), is also inapplicable. The patent in that case was held invalid and the defendant experimented only briefly with an infringing apparatus, abandoning it in favor of a non-infringing alternative. The case of *Maxon Premix Burner Co.* v. *Eclipse Fuel Engineering Co.*, 471 F.2d 308 (7th Cir. 1972), *cert. denied*, 410 U.S. 929 (1973), similarly does not address the issue of systematic exploitation. It concerned a single isolated sale made nine years earlier—"if there was in fact such a sale." *See also Celotex Corp.* v. *V.E. Power Door Corp.*, 204 U.S.P.Q. 636, 638 (E.D.N.Y. 1979) (a single demonstration or trial conducted years earlier).

Bolar also relies upon *Levin* v. *Ripple Twist Mills, Inc.*, 416 F. Supp. 876 (E.D. Pa. 1976), *appeal dismissed*, 549 F.2d 795 (3d Cir. 1977). In *Levin*, however, the court states, in *dictum*, that an experimental use is not actionable unless and until there is a "commercially valuable use." 416 F. Supp. at 881 n.9. Bolar's use is commercially valuable because the test data generated by the use and the FDA approval based upon such test data are *per se* valuable. Each can be assigned or otherwise transferred for consideration.

The CAFC was correct in refusing to excuse Bolar's unauthorized use because Bolar's use *does* interfere with the patentee's statutory right to exclude others from such use.

IV

THERE IS NO CONFLICT BETWEEN THE CAFC'S DECISION AND DECISIONS OF THIS COURT PROHIBITING THE EXTENSION OF PATENT "MONOPOLIES"

Bolar's claim that the decision below extends patent "monoplies" is unfounded. This case is unlike *Brulotte* v. *Thys Co.*, 379 U.S. 29 (1964), cited by Bolar, which involved *post*-expiration royalty and resale restraints imposed by the patentee which would have extended an expired patent. No such post-expiration restraints are sought by Roche Products or sanction-

ed by the CAFC here. The decision below merely enforces the patentee's statutory right to exclude others from using the invention *during* the term of the patent. *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249 (1945), also relied upon by Bolar, was concerned with an attempt to assert a patent against an allegedly infringing machine that was already in the public domain, because "it . . . [the machine's construction] was precisely that of an *expired* patent." 326 U.S. at 254 (emphasis added). In contrast, Roche Products, in seeking only to enforce its statutory right to exclude infringing use of the patented compound *during* the term of an admittedly valid patent, takes nothing from the public domain.[12]

It has long been held by various courts that a patent holder can exercise its right to seek relief during the patent term even though the sale relating to the infringement occurred after the patent expired or occurred outside the geographic area of patent protection. *See, e.g., Radio Corp. of America* v. *Andrea*, 15 F. Supp. 685 (E.D.N.Y. 1936), *modified on other grounds*, 90 F.2d 612 (2d Cir. 1937) (use of patented invention by testing in preparation for non-infringing extraterritorial sale held infringement); *Fulton Co.* v. *Bishop & Babcock Co.*, 17 F.2d 1006 (6th Cir. 1927) and *Motion Picture Patents Co.* v. *Centaur Film Co.*, 217 F. 247 (D.N.J. 1914) (pre-expiration use of patented invention held infringement and authorizing injunction against non-infringing post-expiration sale); *Underwood Typewriter Co.* v. *Elliott-Fisher Co.*, 156 F. 588 (C.C.S.D.N.Y. 1907) (pre-expiration making of patented invention for non-infringing post-expiration sale held infringement).

There is thus no extension of any patent "monopoly" involved in this case nor is there any conflict between the decision below and decisions of this Court, notwithstanding Bolar's assertions to the contrary.

---

[12] For similar reasons, none of the remaining cases cited by Bolar is applicable. Indeed, none involved questions of patent infringement. *See Singer Mfg. Co.* v. *June Mfg. Co.*, 163 U.S. 169 (1896) (trademark case); *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111 (1938) (trademark case); *Upjohn Mfg. Co.* v. *Schweiker*, 681 F.2d 480 (6th Cir. 1982) (FDA marketing case not involving patents).

CONCLUSION

For the reasons stated above, the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

JOHN C. VASSIL,
(Counsel of Record)
STEPHEN R. SMITH
J. ROBERT DAILEY
JANET DORE
Attorneys for Respondent
Roche Products Inc.

Of Counsel:

JACK LIPSON
MICHAEL T. SHOR
RALPH N. DEL DEO